REMARKS

Status of the Claims

Claims 1-4, 6-26 are pending. Claim 5 was canceled. Claims 8-22, 25, and 26 were withdrawn from further consideration as being drawn to non-elected subject matter as a result of a restriction requirement.

By entry of this amendment, claims 2-4, 6-26 have been canceled without disclaimer or prejudice. Applicants reserve the right to pursue the subject matter encompassed in the canceled claims in subsequent continuation or divisional applications.

Claims 1 has been amended by this amendment. New claims 27-65 have been added. Thus, claims 1, and 27-65 are currently under examination.

No new matter has been added by this amendment.

Support for amended claims and the new claims can be found in the specification, Table 1, Table 2, Table 5, Table 6 and the Sequence Listing. Note that SEQ ID NO: 1688 is the genomic sequence where SEQ ID NO: 5502 (201 nucleotides) can be found.

This amendment adds, changes and/or deletes claims in the instant application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claims remain under examination in the application, are presented with an appropriate defined status identifiers. See 37 C.F.R. §1.121(c).

Specification

The Examiner objected to an alleged informality in the specification, stating that it is appropriate to identify each unique sequence with a unique SEQ ID NO identifier. The Examiner required appropriate correction.

The MPEP § 2422.03, and 37 C.F.R. §1.821(c) state that "[t]he requirement for sequence identification numbers, at a minimum, requires that each sequence be assigned a different number for purposes of identification". However, there is no requirement in the rules for the reverse, namely, that each SEQ ID NO be assigned a different sequence. In other words, there is no prohibition that one sequence can have two SEQ ID NOs. Applicants respectfully request the Examiner withdraw the objection.

Claim Objections

The Examiner objected to claims 1-4, 6, 7, 23 and 24 as they allegedly recite non-elected subject matter.

By entry of this amendment, the objections are obviated, and should be withdrawn.

Rejections under 35 USC §112, second paragraph, indefiniteness

The claims are rejected under 35 USC §112, second paragraph, as being allegedly indefinite. Applicants respectfully traverse.

By entry of this amendment, the claims now recite one SNP location, and are clearly defined as to the subject matter they pertain to. Thus, the Examiner is respectfully requested to withdraw the rejections.

Rejections under 35 USC §112, first paragraph, written description

The claims are rejected under 35 USC §112, first paragraph, for allegedly being not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse.

As amended, the claims now specify a single polymorphism SNP hCV163035, rs2276864, within SEQ ID NO: 5502, which is associated with an altered risk of Rheumatoid Arthritis (RA).

Therefore, the rejections under 35 USC §112, first paragraph, for allegedly lack of adequate written description have been overcome. The Examiner is respectfully requested to withdraw the rejections.

Rejections under 35 USC §112, first paragraph, enablement

The claims are rejected under 35 USC §112, first paragraph, for allegedly being not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse.

As amended, the claims are now directed to human subjects, and to the risk of RA within the human subjects.

The Examiner asserted that the methods claimed herein are limited to RF+ samples, citing several references such as *Harrison et al., Lee et al., Begovich et al., and Chen et al.*, in support of the assertion. Those references disclose that certain SNPs are associated with RF+ samples, but not RF- samples.

It is well known that the Examiner bears the initial burden to make a *prima facie* case that the claims are enabled in the specification. As stated in the MPEP, "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)". MPEP §2164.04. A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. §112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. MPEP §2164.04.

Even assuming the Examiner has met his initial burden, applicants can overcome a *prima facie* case of lack of enablement by presenting persuasive arguments, supported by suitable proofs where necessary, that one skilled in the art would be able to make and use the claimed invention using the application as a guide. MPEP §2164.05. It's important to note that the evidence provided by applicants need not be conclusive but merely convincing to one skilled in the art. MPEP §2164.05.

Here, the Examiner's attention is directed to *Van Oene* et al., attached in the enclosed Form PTO/SB/08B. *Van Oene et al*, Arthritis and Rheumatism, 2005; 52: 1993-98. This reference provides convincing data showing that the OR associated with the PTPN22 risk alleles was essentially the same in RF- patients and RF+ patients. *Van Oene et al*, at pp. 1995-96. Thus, it is evident to one with ordinary skill in the art that the same SNP could be associated with risk of RA in both RF+ and RF- patients.

In addition, the small size of the RF- samples in *Begovich et al.* may explain the lack of showing of association of the PTPN22 SNP with risk of RA in RF- patients. With a sufficient number of RF- patients, as the case in *Van Oene et al.*, the effect of the risk allele of the PTPN22 SNP is expected to show in RF- patients. Thus, the *prima facie* case of lack of enablement is overcome, and that applicants' instant invention relating to SNP rs2276864 being associated with all RA subjects is indeed enabled by the specification as filed.

Therefore, the rejections under 35 USC §112, first paragraph, for allegedly lack of enablement have been overcome with the claims amendment and in light of the remarks above. The Examiner is respectfully requested to withdraw the rejections.

Rejections under 35 USC §102(b)

Claims 23 and 24 are rejected under 35 USC §102(b) for allegedly being anticipated by GenBank GI 16874864 (9-Nov-2001).

By entry of this amendment, claims 23 and 24 have been cancelled without disclaimer or prejudice, thus making this rejection moot. The Examiner is respectfully requested to withdraw this rejection.

In conclusion, in light of the amendments and remarks above, Applicants submit that the present application is fully in condition for allowance. Early notice to that effect is earnestly requested.

The Examiner is invited to contact the undersigned via telephone if a phone interview would expedite the prosecution of the instant patent application.

Respectfully submitted,

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